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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,315	09/24/2001	Robert W. Wannemacher	12694/P66821US2 (RIID99-2)	6514

7590

02/07/2005

Office of the Staff Judge Advocate
U.S Army Medical Research and Materiel Command
ATTN: MCMR-JA (Ms. Elizabeth Arwine)
504 Scott Street
Fort Detrick, MD 21702-5012

EXAMINER

VANDERVEGT, FRANCOIS P

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 02/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/960,315	Applicant(s) WANNEMACHER ET AL.	
	Examiner F. Pierre VanderVegt	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17,18,21-27,40 and 44-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17,18,21-27,40 and 44-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date <u>02/03/05</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This application is a continuation of U.S. Application Serial Number 09/523,271; which claims the benefit of the filing date of provisional application 60/124,283.

Claims 1-16 and 28-39 were previously canceled.

New claims 40-46 were previously added.

Claims 19, 20 and 41-43 are presently canceled.

Claims 17, 18, 21-27, 40 and 44-46 are currently pending and are the subject of examination in the present Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 17, 18, 21-27, 40 and 44-46 stand rejected under 35 U.S.C. 102(b) as being anticipated by Thorpe et al (Eur. J. Biochem. [1985] 147:197-206; AV on form PTO-1449).

It was previously stated: "Applicant's claimed method consists of a single step, which is the administration an amount of chemically deglycosylated ricin A chain. The recitation in the claim of inducing a particular titer of anti-ricin antibodies is merely a characterization of the result of practicing the method and does not limit the method itself.

Thorpe teaches the deglycosylation of ricin A chain with sodium metaperiodate and cyanoborohydride at a pH of 3.5 at 4°C (page 198, second column in particular). Thorpe teaches that the level of deglycosylation was dependent upon the incubation time and a maximum of 13 out of the total 18 mannose residues were destroyed (Abstract in particular). Thorpe teaches the administration of 20 µg/kg to rat subjects (Table 3 in particular). While Thorpe is silent regarding the production of ricin-reactive antibodies in the treated subject, Thorpe teaches administration of ricin A chain that has been incompletely deglycosylated in the same manner as that disclosed in the instant specification (page 7, line 17 to page 8, line 5 for example) within the claimed range of administration. Accordingly, the production of antibodies to ricin is inherent to the method of incompletely deglycosylated ricin A chain administration taught by Thorpe. The prior art teaching anticipates the claimed invention."

Applicant's arguments filed November 15, 2004 have been fully considered but they are not persuasive.

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Base claim 17 has been amended to recite that the ricin A-chain lacks about 50% of the mannose residues and most fucose residues of wild type ricin toxin A-chain.

Applicant contends that Thorpe does not anticipate the claimed invention because Thorpe does not teach each and every element. Applicant asserts that Thorpe does not teach the destruction of about 50% of the mannose residues and most fucose residues. However, it is noted that Figures 2 and 3 show that after 60 minutes of $\text{IO}_4/\text{CNBH}_3$ treatment (specifically recited in instant claim 18) about 50% of the mannose is destroyed and Figure 2 further shows that most fucose is destroyed. Thorpe further teaches that the 60-minute composition was administered to animals (Table 2 in particular) and that "the duration of treatment of ricin with $\text{IO}_4/\text{CNBH}_3$ that gives maximal avoidance of reticuloendothelial recognition with least reduction in cytotoxic activity is 60 min under the conditions used in this study" (page 205, last paragraph of column 1 in particular). Accordingly, Thorpe does indeed teach the significance of a ricin A chain lacking about 50% mannose residues.

Applicant further asserts that Thorpe teaches away from the claimed invention because Thorpe teaches that deglycosylation can increase in vivo toxicity up to fourfold. The higher toxicity taught by Thorpe is unquestionable. However, the fact remains that Thorpe does teach the administration of a composition comprising a ricin A chain lacking about 50% of the mannose residues and most of the fucose residues. As stated previously, "Applicant's claimed method consists of a single step, which is the administration an amount of chemically deglycosylated ricin A chain. The recitation in the claim of inducing a particular titer of anti-ricin antibodies is merely a characterization of the result of practicing the method and does not limit the method itself." The fact remains that Thorpe teaches a method of deglycosylated ricin administration that satisfies the metes and bounds of the claims. Accordingly, Thorpe does not teach away from the claimed invention.

However, it is noted that the instant specification teaches the removal of ricin-B chain after deglycosylation, but prior to administration (page 8, lines 6-27 for example). Accordingly, the specification teaches a method of administering deglycosylated ricin-A chain after the removal of deglycosylated B-chain. While Thorpe teaches a method of administering a composition *comprising* deglycosylated ricin A-chain, Thorpe does *not* teach the removal of B-chain prior to administration. Accordingly, amendment of the claim to recite, in a manner consistent with the instant specification, that ricin B-chain is not an active component of the composition used in the claimed method result in the withdrawal of the instant ground of rejection.

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Conclusion

2. No claim is allowed.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

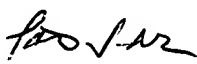
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D.
Patent Examiner
February 2, 2005


PATRICK J. NOLAN, PH.D.
PRIMARY EXAMINER

2/3/05